Massachusetts Department of Public Health (MDPH)
Immunization Program

Vaccine Information Statements: An Important Tool in Vaccine Risk/Benefit Communication

Public concern about possible vaccine adverse events underscores the importance of effective communication with patients or parents about the risks and benefits of vaccination. Vaccine Information Statements (VISs) are an important tool in risk communication. They are also a legal requirement! The following *VIS Questions and Answers* address VIS availability and use.

VIS Basics

1. What is a Vaccine Information Statement (VIS)?

A Vaccine Information Statement (VIS) is a one-page (two-sided) information sheet, produced by CDC. VISs inform vaccine recipients, their parents or legal representatives about the benefits and risks of vaccines. Federal law requires that VISs given out whenever certain vaccinations are given.

2. Why must Vaccine Information Statements (VISs) be used?

VISs are a requirement of the National Childhood Vaccine Injury Act (NCVIA) of 1986. Their purpose is to inform vaccine recipients, or parents of children getting vaccines, about the benefits and risks of vaccines.

3. Which VISs must be used?

A VIS must be provided for any vaccine that is covered by the Vaccine Injury Compensation Program (i.e., appears on the Vaccine Injury Table). As of August 2007, VISs must be used for: DTaP, Td, MMR, polio, hepatitis A, hepatitis B, Hib, varicella, rotavirus, Tdap, HPV, meningococcal, influenza, and pneumococcal conjugate vaccines.

Other VISs are available for pneumococcal polysaccharide, rabies, shingles, yellow fever, typhoid, Japanese encephalitis, anthrax, and smallpox vaccines. Their use is not required by the National Childhood Injury Act, but is strongly encouraged – and they must be used when giving vaccines purchased through a CDC contract.

Providers may add their practice name, address, and phone number to VISs, but they may not change the content. Providers may also supplement VISs with oral or written materials that help vaccine recipients understand the diseases and vaccines; however they may not substitute their own materials for the VISs.

4. When must VISs be given?

Health care providers are required to provide a copy of the relevant VIS to a vaccine recipient or, in the case of a minor, to the parent or legal representative **prior to administration** of each vaccine and **every time** the vaccine is given, including each dose of a multi-dose series. Anyone receiving a covered vaccine should be given the appropriate VIS, adults as well as children. There are several reasons a VIS must be given out with **every** vaccination. The VIS may have been updated between visits, or the health status of the child could have changed (e.g., he or she may have an evolving neurological disorder).

VIS Availability and Distribution

5. What VISs are currently available from the CDC?

VISs for vaccines covered by the NCVIA (as of August 2007), and the dates they were issued, are:

- DTaP (includes DT): 5/17/07
- Td: 6/10/94
- Tdap: 7/12/06 (Interim)
- Hib: 12/16/98
- Hepatitis A: 3/21/06
- Hepatitis B: 7/18/07 (Interim)
- Human papillomavirus (HPV): 2/2/07 (Interim)
- Inactivated influenza: 7/16/07 (Updated annually)
- Live, intranasal influenza: 7/16/07 (Updated annually)
- MMR:1/15/03
- Meningococcal: 8/16/07 (Interim)
- Pneumococcal conjugate: 9/30/02
- Polio: 1/1/00
- Rotavirus: 4/12/06 (Interim)
- Varicella: 1/10/07 (Interim)

6. How can providers in Massachusetts access VISs?

VISs are available online in PDF format on the CDC website: http://www.cdc.gov/vaccines/pubs/vis/default.htm and the Immunization Action Coalition website: http://www.immunize.org/vis. Online VISs should be downloaded by providers and used to make copies for all patients receiving vaccines.

MDPH strongly recommends that providers designate a staff member to be responsible for VISs and to subscribe to receive e-mail notification from CDC of revised or new VIS versions. To subscribe, click on the 'Get E-Mail Updates' link on the CDC VIS page (http://www.cdc.gov/vaccines/pubs/vis/default.htm), and enter your e-mail address. It is the provider's responsibility to provide copies of the most up to date VISs in their office.

7. Are VISs available in languages other than English?

VISs have been translated into 30 languages by the California and Minnesota immunization programs.

Arabic	Hindi	Romanian
Armenian	Hmong	Russian
Bosnian	Ilokano	Samoan
Cambodian	Japanese	Serbo-Croatian
Chinese	Korean	Somali
Croatian	Laotian	Spanish
Farsi	Marshallese	Tagalog
French	Polish	Thai
German	Portuguese	Turkish
Haitian Creole	Punjabi	Vietnamese

Translations can be found on the Immunization Action Coalition's website (www.immunize.org/vis)

8. When do providers have to start using a new VIS?

The date for required use of a new VISs required is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately, particularly if the vaccine's contraindications or adverse event profile have changed significantly since the previous version.

9. Must the patient, parent, or legal representative physically take away a copy of each VIS, or can they simply read a copy?

Ideally the person getting the shot, or their representative, should actually take the VIS home. It contains information that may be needed later (e.g., the recommended vaccine schedule, information about what to do in the case of an adverse reaction). Patients may choose not to take the VIS, but the provider should offer them the opportunity to do so.

Legal Considerations

10. How should providers comply with the law for patients who cannot read a VIS (e.g., patients who are illiterate or blind)?

The NCVIA requires providers to supplement the VISs with "visual presentations" or oral "explanations", as needed. If patients are unable to read the VISs, it is up to the provider to ensure that they have that information. VISs can be read to these patients, or videotapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VISs read. Versions of VISs that are compatible with screen reader devices are available on the CDC website.

11. Are VISs considered to be "informed consent?"

VISs were written to fulfill the information requirements of the NCVIA (42 U.S.C. § 300aa-25). They are not considered informed consent forms; however they do provide detailed information about the risks and benefits associated with vaccinations.

Although the federal government does not require consent, Massachusetts' law requires informed consent from a parent or other legal representative for treatment of a minor. For school-based programs or other programs where a parent is not present at the time of immunization, it is important to consult with your institution's legal counsel about your institution's policies or requirements regarding consent and consent forms.

12. What does "legal representative" mean?

In Massachusetts, a "legal representative" is a parent, legal guardian, or other individual who is qualified by state law to consent to the immunization of a minor. There are some categories of minors which are permitted to consent to treatment on their own, including those who are married, living independently, pregnant or the parent of a child, or reasonably believe themselves to be suffering from or to have come in contact with a dangerous disease (MGL c.112, s.12F).

13. What are the record keeping requirements concerning VISs relative to the patient's medical record?

When giving a vaccine covered by the NCVIA, health care providers must document in the patient's permanent medical record (or in a permanent office log or file) the following information:

- Name of the vaccine administered
- Date of administration of the vaccine
- Manufacturer and lot number of the vaccine
- Name, address, and title (if applicable) of the health care provider administering the vaccine, (This should be the address where the record is kept. If immunizations are given in a shopping mall, for example, the address would be the clinic where the permanent record will reside.)
- Which VIS was given
- Date printed on the VIS (publication date)
- Date on which the VIS was given to the vaccine recipient, parent, or legal representative.

The MDPH Immunization Program also recommends the dose, site, and route of administration be documented, along with the expiration date of the vaccine.

Health care providers are not required to obtain the signature of the patient, or parent or legal representative acknowledging receipt of a VIS, **except** in situations where the parent or legal representative is **not** present at the time of immunization.

14. What are the reporting requirements relative to adverse events following vaccination?

The Vaccine Adverse Event Reporting System (VAERS) is operated by the Food and Drug Administration (FDA) and the CDC. Health care providers **are required** to report any adverse event set forth in the *Vaccine Injury Table* that occurs within the time period specified or within 7 days, if that is longer, following the administration of a vaccine. Providers are also required to report any event listed in a manufacturer's package insert as related to a contraindication or potential adverse event.

Adverse events are reported by completing and submitting a VAERS form. Complete VAERS reports include information about the time interval from administration of a vaccine to the onset of the vaccine related illness, disability, injury, condition, or death; the symptoms and manifestations of such illness, disability, injury, or condition; and the manufacturer and lot number of the vaccine. Filing information is found on the reverse side of the form. Injured individuals, or their parents, or legal guardians may also file VAERS forms for vaccine-related injuries or death.

VAERS forms may be obtained by calling 1-800-822-7967, or by downloading from the Vaccine Adverse Event Reporting System website at http://vaers.hhs.gov/. Adverse events may also be reported and submitted securely online at https://secure.vaers.org/VaersDataEntryintro.htm.

Resources

15. Where else can I find information to help with vaccine risk communication?

Distribution of the VIS is only one step in effective risk communication. The VIS and other vaccine information materials cannot replace dialogue between provider and parent/patient. For additional information regarding vaccines, vaccine preventable diseases and risk communication, consider the following resources:

a. CDC's Vaccines and Immunizations web site at: http://www.cdc.gov/vaccines,

b. CDC National Immunization Information Hotline at: 800-232-4636 (800-CDC-INFO) or 888-232-6348 (TTY),

c. MDPH Immunization Program at: 888-658-2850 or 617-983-6800,

d. MDPH's Immunization web site at: http://www.mass.gov/dph/cdc/epii/imm/imm.htm,

e. The Children's Hospital of Philadelphia web site at: http://www.vaccine.chop.edu,

f. The Immunization Action Coalition (IAC) web site at: www.immunize.org,

g. The American Academy of Pediatrics' (AAP) *2006 Redbook: Report of the Committee on Infectious Diseases*,

h. The reports and recommendations of the Advisory Committee on Immunization Practices (ACIP) published in the *Morbidity and Mortality Weekly Report*, available on the CDC web site at: http://www.cdc.gov/vaccines/recs/acip/default.htm,

i. Manufacturers' package inserts.